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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/042,431	10/25/2001	Sean A. McCarthy	10147-6U2	5729

7590 03/15/2004

INTELLECTUAL PROPERTY GROUP
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CAMBRIDGE, MA 02139

[REDACTED] EXAMINER

NASHED, NASHAAT T

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1652

DATE MAILED: 03/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/042,431	MCCARTHY ET AL.	
	Examiner	Art Unit	
	Nashaat T. Nashed, Ph. D.	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 28 January 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 52-75 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 52-75 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All
 - b) Some *
 - c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/8/02</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

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Applicant's election with traverse of Group 25, claims 19, 20, 22, and 28-30 in the paper filed January 28, 2004 is acknowledged. The traversal is on the ground(s) that the amino acid sequence of SEQ ID NO: 49 is a fragment of the amino acid of SEQ ID NO: 47, and thus, searching one sequence will be sufficient to obtain all the relevant prior art. This is not found persuasive, and the restriction requirement between Groups 25 and 27 has been vacated.

The requirement is still deemed proper and is therefore made FINAL.

The application has been amended as requested in the communication filed January 28, 2004. Accordingly, claims 19-22 and 24-51 have been canceled, and new claims 52-75 have been entered and under consideration.

The abstract of the disclosure is objected to because it does not describe the claimed invention. Correction is required. See MPEP § 608.01(b).

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: Method of Identifying Inhibitors of the Human Lipase TANGO 294.

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

The use of the trademark name TaqManTM, see for example pages 72 and 74, has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 52-75 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility.

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Applicants disclose human nucleic acid sequences of SEQ ID NO's: 45 and 46 encoding the polypeptide sequences of SEQ ID NO's: 47 and 49, respectively, which are named TANGO 294. SEQ ID NO: 49 is derived from SEQ ID NO: 47 by truncation of the N-terminus by 33 amino acid residues. Based on reasonable sequence homology (50-62%) to known lipases, the protein of SEQ ID NO: 47 and 49 are thought to be human lipases, which is a reasonable and acceptable asserted utility. Contrary to the assertion of the applicants that the amino acid sequence of TANGO 294 is 75% homologues to lingual and gastric lipase from rat (Swissport Accession number P04634), see the specification, page 71 lines 3-9, the homology obtained by the examiner for SEQ ID NO: 49 is only 55.9% corresponding to 213 matches, 63 conservative, and 93 mismatches. The specification, however, does not identify any specific or substantial credible chemical or biological function or use. The specification describes non-specific functions for the protein, nucleic acid, and antibodies, let alone molecule that bind, inhibits or activate TANGO 294, see for example paragraphs 251-256. The utilities disclosed for the polypeptide of SEQ ID NO: 47 and 49 are possible utilities, which are extrapolated from the utilities of known lipases. Almost all of the possible utilities are base on sequence homology to SEQ ID NO: 49, but it is well accepted in the art that sequence homology does not impart a functional homology. There are many human lipases each of which have a specific function and biological role based on that function. The specification does not provide any relation ship between TANGO 249 and any specific disease or syndrome or any possible use of the compounds obtained by the claimed method. The specification does not even show that the polypeptide of SEQ ID NO: 47 and 49 have any enzymatic activities using any substrate. It appears that the main utility of the products of the claimed method is to carry out further research to identify the biological function and possible diseases associated with said function. Substantial utility defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utility. Thus, the claimed invention has no specific or substantial asserted utility.

Applicant is referred to the revised interim guidelines concerning compliance with utility requirement of 35 U.S.C. 101, published in the Official Gazette and also available at www.uspto.gov.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 52-75 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or

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substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the compounds identified by the claimed method.

Claims 52-58, and 66-70 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 52-58, and 66-70 are directed to a method of identifying compound that binds and/or modulate all possible TANGO 294 proteins which are 90% homologues to SEQ ID NO's: 47 and 49. The specification, however, only provides a single representative species from human encompassed by these claims, which applicants assert has a lipase activity. There is no disclosure of any particular structure to function/activity relationship in the single disclosed species. The specification also fails to describe additional representative species of the TANGO 294 proteins by any identifying structural characteristics or properties, for which no predictability of structure is apparent. Given this lack of additional representative species as encompassed by the claims, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as the specification lacks a sufficient written description for enablement based on deposit requirement.

The invention appears to employ a novel gene named EpT294. Since the gene is essential to the claimed invention, it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. The enablement requirement of 35 U.S.C. § 112 may be satisfied by a deposit of the cDNA or transformed *E. coli* comprising the cDNA. The specification does not disclose a repeatable process to obtain the gene and it is not apparent if the DNA sequences are readily available to the public. Accordingly, it is deemed that a deposit of the gene should have been made in accordance with 37 C.F.R. § 1.801-1.809.

It is noted that the applicant has deposited EpT294 under the terms of the Budapest treaty, see the specification, page 156, paragraph 497, but there is no indication in the specification as to public availability. Since the deposit was made under the terms of the Budapest Treaty, then an affidavit or declaration by the applicant, or a statement by an attorney of record over his/her signature and registration number, stating that the specific gene has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of the patent, would satisfy the deposit requirement made herein.

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Claims 52-75 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

Claims 52-75 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is not enabling for any claims. The specification does not enable any person skilled in the art to make and use the invention commensurate in scope with these claims. The claims are broader than the enablement provided by the disclosure with regard to the carry out the claimed method and the use of its product in addition to practicing the method with TANGO 294 having 90% identity to SEQ ID NO: 49 and 47. Factors to be considered in determining whether undue experimentation is required, are summarized *In re Wands* [858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)]. The Wands factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim.

The nature and breadth of the claimed invention encompasses a method of identifying compound that bind or modulate the activities of proteins having 90% sequence identity to SEQ ID NO: 47 and 49. The specification provides an assay describing a human nucleic acid encoding a protein named TANGO 294 which is thought to be a lipase by the applicants based on a reasonable sequence homology to known lipases. As indicated above, the specification has failed to provide a specific or substantial utility for the polypeptide and indulged in speculation of various possible chemical and biological functions. The specification failed to identify a specific substrate by which the enzymatic activity can be assayed, or any use for the compounds that binds or modulates the activity of TANGO 294 and its variants. While molecular biological techniques and genetic manipulation to make the TANGO 294 variants are known in the prior art and the skill of the artisan are well developed, knowledge regarding the relationship between TANGO 294 and any disease or syndrome, an assay method for the catalytic activity of TANGO 294, the enzymatic activity of SEQ ID NO: 47 or its fragment residues 15-423, or SEQ ID NO: 49 is lacking. Thus, searching for a TANGO 294 having 90% sequence identity to SEQ ID NO: 47 or 49, identify its biological or chemical activity and its association with a disease or syndrome, develop an assay method for the catalytic activity, and identify compounds that bind or modulate the catalytic activity and identify a disease or syndrome which said compounds can treat is well outside the realm of routine experimentation and predictability in the art of success is extremely low. The amount of experimentation to identify the chemical or biological activity of the proteins SEQ ID NO's: 47 and 49, a 90% protein homologous to SEQ ID NO: 47 and 49, its biological or chemical functions, or association to any disease or syndrome is enormous. Since routine experimentation in the art does not include screening for a biological and chemical function, or identifying a proteins having 90% identity with SEQ ID NO: 47 and/or 49 and its biological and chemical function, and identify modulated of said protein to treat a disease to be

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identified at a later time where the expectation of obtaining the desired modulator and its a possible use for it is unpredictable, the Examiner finds that one skilled in the art would require additional guidance, such as information regarding a specific disease or syndrome which can be treated with the product of the claimed method, any other use of the product of the claimed method, a specific substrate for the polypeptides of SEQ ID NO: 47 and 49, and proteins having 90% sequence homology to SEQ ID NO: 47 and/or 49 as well as their biological function. Without such guidance, the experimentation left to those skilled in the art is undue.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nashaat T. Nashed, Ph. D. whose telephone number is 571-272-0934. The examiner can normally be reached on MTTF.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Nashaat T. Nashed, Ph. D.
Primary Examiner
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